**U.S. Department of Labor**

Office of Administrative Law Judges
800 K Street, NW, Suite 400-N
Washington, DC 20001-8002

(202) 693-7300
(202) 693-7365 (FAX)

**Issue date: 26Apr2002**

In the Matter of:

1996 BTD 00005

CLARENCE DAVIS (Deceased Miner)

v.

TENNESSEE CONSOLIDATED COAL COMPANY,

Employer

and

DIRECTOR OFFICE OF WORKERS' COMPENSATION PROGRAMS,

Party-In-Interest

Appearances:

Thomas A. Grooms, Esq.
For the U.S. Department of Labor

Mark Solomon, Esq.
For the Employer

BEFORE: CORRECTED

MOLLIE W. NEAL
Administrative Law Judge

*DECISION AND ORDER*

This proceeding arises out of a claim for medical treatment benefits under the provisions of Title IV of the Federal Coal Mine Health and Safety Act of 1969, as amended, 30 U.S.C. 901 et seq. ("the Act"), and the implementing regulations at 20 C.F.R. §725.701 et. seq. The Act provides benefits to coal miners who are totally disabled due to pneumoconiosis and to surviving dependents of miners whose death was due to coal workers pneumoconiosis. Pneumoconiosis is defined as a "chronic dust disease of the lung and its sequelae, including respiratory and pulmonary impairments, arising out of coal mine employment." This controversy involves the Director, Office of Workers' Compensation Programs', determination to allow medical benefits for lung transplant services, which are not covered under the

guidelines contained in DOL's Black Lung Provider Manuals ("Provider Manuals") published in 1980, 1985, and 1990.

Clarence Davis (the deceased "miner") worked 19 years as a coal miner, from 1968 until June 26, 1987. He had a twenty-eight year smoking history and was reported to have smoked as many as three packs of cigarettes daily, commencing in 1964 and ending in 1992. Mr. Davis filed a claim for black lung benefits on March 26, 1991, and was awarded benefits by the Office of Workers' Compensation Programs (OWCP)[1] on December 5, 1991. Tennessee Consolidated Coal Co., the responsible coal mine operator (the "Employer"), accepted liability for the claim on January 3, 1992.

In November 1995, Dr. James Lloyd requested approval from OWCP to evaluate the miner for end stage lung disease and a lung transplantation. He indicated that the miner had severe coal workers' pneumoconiosis which resulted in the deterioration of his lung function (FEV1#24%). Dr. Lloyd stated that the miner's pneumoconiosis had been nonresponsive to all known medical treatments, leaving lung transplant his only option. In response, DOL sought expert medical opinions on the question of whether a lung transplant was a necessary treatment related to the miner's coal workers' pneumoconiosis. (DX 16). Drs. Samuel Spagnolo, Leon Cander and Michael Sherman submitted written opinions.

Dr. Leon Cander reviewed the miner's medical records and history and noted that the chest x-ray and CT revealed findings consistent with coal workers' pneumoconiosis, silicosis, and extensive emphysematous change with multiple large and small bullae documenting the presence of extensive end-stage lung disease. He noted a rapid decrement in lung function, and rapid development of diffuse bulla formation which had encroached on functional lung volume. [2] He felt that the miner's major pulmonary problem was chronic obstructive lung disease (diffuse emphysema), caused, in part, by the occupational inhalation of coal mine dust. He also found silicosis caused by coal mine dust, resulting in superimposed interstitial silicotic fibrosis on diffuse emphysema. Dr. Cander concluded that, the miner's emphysema was related to his extensive history of cigarette smoking, and that coal dust was also a significant cause. Dr. Cander reached this conclusion relying, in part, on medical studies which document that occupational inhalation of coal mine dust is a cause of chronic obstructive lung disease. (DX 18)

Dr. Samuel Spagnolo reviewed the miner's medical records and reached a contrary conclusion. He diagnosed simple coal workers' pneumoconiosis and bullous emphysema with moderate airflow obstruction. He concluded that pneumoconiosis was not a substantial contributing cause to the miner's bullous lung disease or airflow obstruction, and that it had not substantially hastened a loss of lung function. He thought that the miner's severe bullous emphysema was related to cigarette use. He opined that the miner's lung impairment was essentially, if not totally, related to severe emphysema and resulting moderate air flow obstruction caused by his long cigarette use. (DX 15).

Dr. Michael Sherman reviewed the miner's medical records and history. He noted the chest x-

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[1] "OWCP" is the division of the Employment Standards Administration of the U.S. Department of Labor ("DOL") responsible for the administration of the Black Lung program.

[2] See also the evaluation of Dr. Gunter, the miner's treating physician, at (DX 9), in which severe dyspnea on exertion secondary to COPD was reported.

ray findings in November 1995 were "consistent with diffuse bullous emphysema and fibrosis secondary to coal miner's pneumoconiosis/progressive massive fibrosis. He also noted a history of roentgenographic findings suggestive of occupational exposure as the cause of end stage lung disease. Dr. Sherman concluded that the miner's condition was due to emphysema caused by coal dust and cigarette smoke inhalation, as well as pulmonary fibrosis from coal dust inhalation. He recognized that coal mine dust was known to cause coal macules, coal nodules, progressive massive fibrosis, and chronic obstructive lung disease (including emphysema). Dr. Sherman concluded the while it was likely that Mr. Davis' emphysema was due, in part, to his long history of cigarette smoking, it was equally likely that coal dust inhalation was also a significant cause. Dr. Sherman indicated that, in addition to emphysema, Mr. Davis had progressive reduction in total lung capacity, and evidence of progressive massive fibrosis and anthrosilicosis. He concluded that the superimposition of this restrictive lung disease with emphysema contributed to the miner's severe pulmonary impairment. (DX 21)

Dr. James Lloyd submitted Vanderbilt Medical Center's [3] evaluation of the miner which disclosed extensive emphysematous changes throughout both lungs with large and small bullae, multiple small focal calcification, in addition to multiple small nodules in fewer abnormal areas of the lung consistent with pneumoconiosis, bilateral bulbous lung changes with superimposed emphysema, and bilateral fibrosis and small nodular changes in the right left lobe, extensive end stage lung disease. Dr. Lloyd stated his opinion as to why the lung transplant was necessary and the reasons he believed coal workers' pneumoconiosis contributed to the miner's end stage lung disease. He indicated that the miner's functional capacity was extremely limited, and that the inhalation of coal dust had caused coal workers' pneumoconiosis and associated emphysema which threatened his life. He noted that the miner's decline in spirometric airflow was far more rapid than occurs with simple smoke related airways obstruction. Computed tomographic scan showed diffuse disease. He indicated the miner had concomitant pulmonary fibrosis, most likely related to complicating silicosis from his mining experience. He concluded that all these factors document that pneumoconiosis is the cause of the miner's end stage lung disease. (DX 19)

Based on the physician opinions, the district director, OWCP, authorized the lung transplant as necessary treatment for the miner's pneumoconiosis. The miner underwent lung transplant at Vanderbilt Medical Center on April 15, 1996. The operation was performed by Dr. Richard Pierson.

The coal mine operator was notified of its responsibility for the payment of reasonable and necessary costs attendant to the lung transplant. Employers declined to make payment for such costs and the matter was referred to the Office of Administrative Law Judges on August 16, 1996.[4] Several attempts to schedule a hearing were unsuccessful due to the unavailability of the attorneys. On November 23, 1998, a notice of hearing and pre-hearing order issued, which included an order closing discovery and

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[3] In February of 1995, Vanderbilt Medical Center was approved by the Health Care Financing Administration (HCFA) as a Medicare heart/lung transplant facility. Transplants performed on Medicare beneficiaries at the facility after that date were covered and paid by Medicare program under the usual claims procedure.

[4] The miner under went unilateral lung transplant operation on April 16, 1996. He died on September 23, 1996. The death certificate listed the causes of death as respiratory arrest, hemothorax, chronic obstructive pulmonary disease, and black lung.

scheduling the hearing for February 26, 1999. Upon joint motion of the parties, the discovery cut off date and the hearing was again rescheduled. On April 9, 1999, Employer filed a motion for summary decision. The motion was not accompanied by affidavits, answers to interrogatories, transcripts of depositions of witnesses, or other supporting documentation. The Director responded to the motion on May 17, 1999.

Employer seeks judgment as a matter of law, on the grounds that the miner's lung transplant was not a reimbursable medical expense under the Act. Employer asserts that, heretofore, Department of Labor ("DOL") had a longstanding "substantive" rule, evidenced by the statement in its Black Lung Provider Manuals for 1985 and 1990, that organ transplants are not reimbursable under the Act. Yet, in this case, DOL for the first time, and without any prior notice, took the position that the medical expenses incurred for the miner's lung transplant are reimbursable. Employer contends that DOL's unilateral reversal of its policy of excluding lung transplants from coverage violates the Administrative Procedure Act (the "APA").

Employer also contends that the opinions of Drs. Cander and Sherman do not constitute substantial evidence that Mr. Davis' treatment is reimbursable under the Act. Employer maintains that the physicians' reliance on scientific studies is insufficient to prove causation in the individual miner's case, citing as authority for its position *General Electric Co. v. Joiner*, 522 U.S. 136 (1993); and *Daubert v. Merrell Dow Pharmaceutical. Inc*., 509 U.S. 579. Rather, Employer urges that the Director had the burden of proving that Mr. Davis'chronic obstructive pulmonary disease was caused by coal mine dust exposure. Except for this general objection, the Employer does not challenge any specific medical expense as unnecessary or unrelated to the treatment of the miner's coal workers' pneumoconiosis. Employer has not submitted medical expert opinions to rebut the opinions of the physicians DOL relied upon in reaching its determination of the necessity for the lung transplant as a related medical treatment.

The parties argued their respective positions on the Employer's Motion for Summary Decision at the formal hearing on August 19, 1999. The record was left open to allow Employer an opportunity to advise the Court if further discovery would be necessary, based on DOL's witness testimony, relating to the decision making processes leading up to the approval of the miner's lung transplant as a reimbursable medical expense. Thereafter, on September 10, 1999, Employer filed a Request for Production of Documents. On October 18, 1999, the Director filed a Motion for a Protective Order. The Director maintains that there is only one issue, i.e., whether the statement contained in the provider manuals published by the Director constitutes a "rule" which could only be abrogated by the publication of a new rule under the Administrative Procedure Act ("APA"). The Director asserts that the discovery requests seek materials which are irrelevant to the issue, and that the scope of the documents requested is over broad, oppressive, and unduly burdensome. Employer responded that the discovery requests seek information relevant to DOL's rule making process and its implementation of the transplant reimbursement policy. First, Employer claims that DOL's Black Lung Provider Manuals provide an incomplete picture of whether DOL treats the reimbursement "guidelines" contained in the manuals as substantive rules by which third parties are bound. Secondly, Employer asserts that DOL provides instructional guidelines to "secondary payers," "bill payment contractors" and "employees of the Social Security Administration" relating to reimbursable medical services which are relevant to the inquiry in this case, and which have not been made a part of the record.

The following findings and conclusions are based upon my thorough review and analysis of the entire record, the arguments of the parties, and the applicable statutory provisions, regulations, and case law.

II.

*ISSUES*

(1) Whether the Employer's Request for Production of Documents should be denied as over broad and irrelevant.

(2) Whether the medical services for which reimbursement is claimed were necessary and related to the treatment of the miner's coal workers' pneumoconiosis.

(3) Whether the Director's determination to cover the lung transplant in this case as an allowable medical expense was "rule making" which required notice and comment under the Administrative Procedure Act.

(4) Whether Director's action of authorizing lung transplant as a covered reimbursable medical expense under the Black Lung Act was arbitrary and capricious agency action.

III.

1. Request for Production of Documents

At the hearing, the Department of Labor submitted complete copies of its Provider Manuals for 1985 and 1990. Employer did not object to the admission of those manuals, but requested an opportunity to consider if it wanted to identify additional discover calculated to paint with more clarity the process by which the Department reached its determination to approve the medical necessity for the miner's lung transplant. Employer alleged that the Provider Manuals were part of a larger process which is relevant to the consideration of the issues raised herein. Subsequent to the hearing, Employer filed a Motion to Produce, seeking the production of the following categories of documents from January 1, 1985 to the present:

(1) All informational material and guidelines provided to any payment contractor, including Computer Sciences Corporation (C.S.C.)[5] explaining the rules or procedures for payment or rejection medical bills submitted for payment under the Act.

[5] C.S.C., a worldwide computer software company that has knowledge and experience in large Medicaid programs, administers bill processing, accounting, and customer services for the medical benefits component of the Department of Labor's Federal Black Lung Program.

(2) all contracts or other documents evidencing a contractual relationship between DOL and any bill payment contractor, and documents related thereto, concerning the payment or rejection of medical bills submitted for payment under the Act;

(3) all documents relating to the reimbursement of payments between DOL and the United Mine Workers of America Combined Benefit Fund, and its predecessors relating to medical services coverage, including organ transplants;

(4) documents relating to DOL's Provider Manuals Federal Black Lung Program, dated 1985 and 1990, including bulletins, replacement pages, or modifications issued during the relevant period.

The Director objects to all requests for production on the same grounds. First, the Director argues that the documents have no relevance to the issues raised in Employer's Motion for Summary Decision, i.e. whether the statement of noncoverage of organ transplants in the Provider Manuals is a "rule" within the meaning of the APA, or whether the Director's decision to allow coverage for the lung transplant should have been made pursuant to the APA's notice and comment "rulemaking" requirements. Second, DOL argues that there is no logical connection between what is sought and the sole issue in this case, i.e. whether the medical treatment for which reimbursement is sought was necessary and related to the treatment of coal workers' pneumoconiosis. Thirdly, DOL argues that the temporal scope of the requests and the breadth of the documents sought are over broad and unduly burdensome.

The principle is generally accepted in federal pre-trial practice that discovery provisions of the federal rules should be applied broadly and liberally to allow the parties to obtain the fullest possible knowledge of the issues and facts. *Hickman v. Taylor*, 329 U.S. 495 (1947). The underlying purpose of this liberal rule is to facilitate trial preparation, prevent surprise, and promote the resolutions of cases on the merits. Such motions for discovery must however be filed within the time prescribed by the rules or ordered by the Court. In black lung proceedings, a party may be allowed to engage in post hearing discovery and to submit rebuttal evidence, if the opposing party is allowed to introduce new evidenced outside the 20-day rule prescribed in Section 725.456 of the regulations. Here, all of the document's Employer seeks relate to issues identified by the Employer in its pre-hearing statement of December 22, 1998. There is no record that discovery, calculated to obtain facts relating to those issues, was initiated within the discovery cut off dates established in the pre-hearing scheduling order, (which was extended prior to hearing on two occasions at Employer's request). Upon my review of the entire record and Employer's Motion to Produce, I find the post hearing discovery efforts of the Employer to be foreclosed by my prior pre-hearing orders. The complete copies of the Black Lung Provider Manuals (collectively referred to as the "Manual"), insofar as they are relevant to this proceeding, do not contain new information for which Employer is entitled to develop post-hearing rebuttal. Employer cannot, and does not, claim that the information in the Manual creates an element of "surprise" which would preclude the defense of the claim for reimbursement of medical expenses. For the purpose of this proceeding, the only issue before me relates to the Manual's Section 2.5 exclusion of lung transplants from coverage as medical benefits under the Act. Where, as here, attempts were not made prior to the hearing to develop the record regarding the practices and procedures relevant to DOL's action, I find no basis to allow such discovery post-hearing. OCWP's practices and procedures, and the reasons OWCP did not apply Section 2.5 of the Black Lung provider manual (1985 editions) in this case were fully set forth in the case

file and in witness testimony at the hearing.

After a full review of the transcript of the hearing and the documents in the record, I agree with the Director that the information requested in Requests 1, 2, and 3 is not relevant to the issue presented in this matter. I also agree that Requests No. 4 and 5 are over broad and unduly burdensome. Accordingly, the Director's motion for a protective order is granted.

2. Whether the medical treatment services for which reimbursement is claimed were necessary and related to the treatment of the miner's coal workers' pneumoconiosis

Black Lung Benefits Program

Under the Black Lung Benefits Act, coal miners or their eligible survivors are compensated for total disability or death due to coal workers' pneumoconiosis under two programs: Part B", *30 U.S.C. §§921-925*, and "Part C", *30 U.S.C. §§931-945*.[6] The Part B program became effective on December 30, 1969, and terminated for new claims on June 30, 1973. Part B claims were filed with SSA and adjudicated under regulations published by the Secretary of Health, Education, and Welfare ("HEW"). Part B of the Act does not provide for health care benefits, and benefits awarded under Part B are paid by the U.S. Treasury from general revenues. *30 U.S.C. 921-925*. *See Mullins Coal Co. v. Director, Office of Workers' Compensation Programs*, 108 S. Ct. 427, 429 (1987). Part B claims are adjudicated in accordance with procedures specified in Section 205 of the Social Security Act*. 42 U.S.C. §405*, incorporated into 30 U.S.C. §923(b). Part C claims, (claims filed after July 1, 1973) are filed with the Department of Labor, if the state does not have an approved workers' compensation law [7], 30 U.S.C. §931, and are adjudicated under DOL's regulations. 30 U.S.C. §§902(f), 932, 936.[8] Part C is administered by the Director, Office of Workers' Compensation Programs ("the Director") pursuant to regulations promulgated by the Secretary of Labor. *See generally, Elliot Coal Mining Co., Inc. v. Director, Office of Workers' Compensation Programs* 17 F. 3d. 616 (3d Cir. 1994) Here, the claim

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[6] *See* Title IV of the Federal Coal Mine Health and Safety Act of 1969, 83 Stat. 792, 30 U.S.C.§801 et. Seq, was amended by the Black Lung Benefits Act of 1972, 86 Stat. 150, 30 U.S.C. §901 et seq., the Black Lung Benefits Revenue Act of 1977, 92 Stat. 11, the Black Lung Benefits Reform Act of 1977, 92 Stat 95, the Black Lung Amendments of 1981, 95 Stat. 1643.

[7] Part C establishes an employer funded workers' compensation program to provide benefits, in cooperation with states for total disability or death due to pneumoconiosis. See H.R. Rep. No. 460, supra at 26-28; S. R. No. 209, 95th Cong., 1st Sess. 13-14 (1977); *see also Strike v. Director Office of Workers' Compensation Programs*, 817 F. 2d 395, 397 (7th Cir. 1987).

[8] The claims procedure contained in the Longshoreman Harbor Worker's Compensation Act. ("LHCWA") *33 U.S. C. §§901-952(Supp. IV 1987*), is incorporated in the Black Lung Benefits Act at 30 U.S.C. §932(a). Similarly, the provisions of 33 U.S.C. 919 (d) the LHCWA which contemplate an Administrative Procedure Act ("APA") trial under *5 U.S.C. § 554*, are incorporated by reference into the Black Lung Benefits Act.

was filed under Part C of the Act, and the regulations found at *20 C.F.R. 725.701-725.707* apply. Medical benefits under Part C claims are paid by the mine operator that last employed the miner or by its insurance carrier *20 C.F.R. Part 725, Sub Part F (1987)*, or by the Black Lung Disability Trust Fund.

A claimant is entitled to medical benefits under Part C of the Act for the cost of medical treatment incurred as a result of his pneumoconiosis.[9] *See 20 C.F.R. §725.701(b). 30 U.S.C. 902. See also Lute v. Split Vein Coal Co.*, 11 Black Lung Rep. (MB) 1-82, 1-84 (1987). *Doris Coal Company v. Director, Office of Workers' Compensation Programs [Stilner]*, 938 F. 2d. 492 (4th Cir. 1991). Section 725.707 sets forth the procedure for disputes concerning medical benefits. The procedure for determining entitlement to medical benefits is a two-stage procedure. First, a determination of liability must be made which involves the question of whether the miner is totally disabled from pneumoconiosis. Once a miner has been determined to be totally disabled from pneumoconiosis, the employer/operator is liable for medical bills incurred in the treatment of the disease.[10] At the second stage, the sole question is one of whether the medical expenses claimed are related to the miner's pneumoconiosis.

As previously indicated, the determination of liability for disability benefits for the deceased miner was made in 1991 and the Employer accepted liability. Thus, the only issue presented here is whether the cost of the miner's medical services and care associated with his lung transplant are reimbursable under the Act as reasonable and necessary for the treatment of his pneumoconiosis. In the Sixth Circuit, the Claimant (in this case the Director, OWCP) has the burden of proving by a preponderance of the evidence that the treatment is related to the miner's totally disabling pneumoconiosis. *Glen Coal Co. v. Seals*, 147 F. 3d 502 (6th Cir. 1998). [11] Employer contends that the opinions of Drs. Cander and Sherman do not constitute substantial evidence that the miner's treatment is reimbursable under the Act. In support of its claim, it suggests that the Director has the burden of proving that Mr. Davis' chronic obstructive pulmonary disease (emphysema) was caused by coal dust exposure. Generally, a challenge to the existence of pneumoconiosis at this phase of the proceeding is not the relevant inquiry. Only the necessity of medical charges for the treatment of pneumoconiosis and related disorders or charges unrelated to

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[9] The term, "pneumoconiosis", incorporates the legal distinction between "clinical" and "legal" pneumoconiosis which the Courts have uniformly adopted as the two forms of lung disease compensable under the Act. "Clinical" pneumoconiosis is defined as the medical condition which only encompasses lung diseases caused by fibrotic reaction of lung tissue to inhaled coal dust, and "legal" pneumoconiosis includes any chronic lung disease, significantly related to or substantially aggravated by dust exposure in coal mine employment. This legal distinction between the two forms of the disease is well settled in the Sixth Circuit, the jurisdiction within which this claim arises. *See Campbell v. Consolidation Coal Co.*, 811 F.2d 302, 304 (6th Cir. 1987). See also *Peabody Coal Co. v. Holskey*, 888 F. 2d 440, 442 (6th Cir. 1989); *Cornett v. Benham Coal Inc.*, 227 F. 3d 569, 575 (6th Cir. 2000)

[10] Such medical benefits, include surgical and other attendance and treatment, nursing and hospital services, medicine, and apparatus, and any other medical service or supply for such periods as the nature of the miner's pneumoconiosis and ancillary pulmonary conditions and disability require. *20 C.F. R. 725.701(A).*

[11] This cases arises in the jurisdiction of the Sixth Circuit Court of Appeals, as the miner's last coal mine employment was in Tennessee. *Shupe v. Director, OWCP*, 12 BLR 1-200 (1989) (en banc).

pneumoconiosis may be challenged. *See, Doris Coal Co. v. Director, OWCP*, 938 F. 2d 492 (4th Cir. 1991). The more narrow question is whether the treatment of the miner's end stage lung disease (which included chronic obstructive lung disease [emphysema]) by lung transplant was necessary for the treatment of coal workers' pneumoconiosis. Based on the board definition of "legal" pneumoconiosis , the burden of showing that the medical expenses were necessary to treatment of pneumoconiosis may be met if the treatment relates to any pulmonary condition resulting from, significantly related to, or substantially aggravated by the miner's pneumoconiosis. *Doris Coal Co., supra,* 938 F. 2d 497. *See also Cornett v. Benham Coal, Inc*. 227 F. 2d 3d 569 (6th Cir. 2000) (definition of "legal" pneumoconiosis) The Sixth Circuit has indicated that the question is one of what constitutes being "related to pneumoconiosis" within the meaning of Section 725.701(b).[12] Both Drs. Cander and Sherman concluded that the miner's diffuse emphysema was caused, at least in part, by occupational inhalation of coal dust. Both relied, in part, on medical studies which document that occupation inhalation of coal mine dust is a cause of chronic obstructive disease. Dr. Cander noted rapid decrement in lung function and rapid development of diffuse bulla formation which had encroached on functional lung volume. He also found silicosis caused by coal mine dust, resulting in superimposed interstitial silicotoic fibrosis and diffuse emphysema. Dr. Sherman concluded that the miner's emphysema was due, in part, to cigarette smoking, but could not rule out coal dust inhalation as a significant cause (recognizing that coal dust as a known cause of chronic obstructive lung disease). He also noted progressive reduction in total lung capacity and progressive massive fibrosis and anthrosilicosis. Both conditions fall within the definition of pneumoconiosis found at 20 C.F.R. 718.201. Both physicians' opinions stand squarely for the proposition that the miner's emphysema, without regard for its cause, "combined with his pneumoconiosis to cause a sum of disease greater than the two parts." Both opinions support a finding that emphysema was related to or, at least, aggravated by the miner's coal workers' pneumoconiosis. As such, the opinions of the Director's medical experts document that the miner's emphysema (chronic obstructive pulmonary disease) was related to his pneumoconiosis.

Furthermore, Dr. Lloyd provided a most compelling basis for concluding that the lung transplant was necessary for the treatment of the miner's pneumoconiosis. Specifically, he indicated that Mr. Davis' functional capacity was extremely limited, and the inhalation of coal dust had caused coal workers' pneumoconiosis and associated emphysema which threatened his life. He also noted a decline in the spirometric airflow which was far more rapid than that which occurs with simple smoke related airways disease. He concluded pneumoconiosis was the cause of the miner's multifactorial end stage lung disease. This compelling medical evidence stands uncontroverted in the record. As such, I find the opinions of Drs. Sherman, Cander and Lloyd outweigh the contrary opinion of Dr. Spagnolo. I further find that the Director has met its burden of proving that the services associated with the miner's lung transplant were related to his coal workers' pneumoconiosis. As the Employer has not contested any of the services claimed as unrelated to pneumoconiosis, I find Employer liable for all expenses in this record for which the Director seeks reimbursement.

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[12] Section 725.701(b) provides that a responsible operator "... shall furnish a miner entitled to benefits under this part with such [treatment] as the nature of the miner's pneumoconiosis and ancillary pulmonary conditions and disability require."

3. Whether Director's Approval of the Lung Transplant, which was excluded from coverage in DOL's Black Lung Provider Manual, constituted rule making which violated the notice and comment requirements of the APA.

Section 936 of the Black Lung Benefits Act provides that the Secretary of Labor is authorized to issue such regulations as may be appropriate to carry out the provisions of the Act. Such regulations must be issued in conformity with Section 553 of Title 5 of the Administrative Procedure Act ("APA"). Section 553 of the APA requires agencies to provide notice of proposed rule making, and an opportunity for public comment prior to a rule's promulgation, amendment, modification, or repeal.5 U.S.C. §533(a) and (c). Pursuant to the statutory delegation of authority, the Secretary issued the Part 725 regulations, which set forth the procedures and standards to be applied in filing, processing, adjudication, and payment of claims filed under Part C of the Act. Section 725.701 sets forth what services miner is entitled to.[13] (Tr. 35). To assist providers of medical services under the Black Lung program, DOL published the provider manuals which explain its billing practices and procedures for medical services related to coal workers' pneumoconiosis..

The Black Lung Provider Manual is developed in consultation with medical experts to administer the program and oversee payment for services. The Manual is intended to be an instructional aide to health care providers who provide services to individuals totally disabled by coal workers' pneumoconiosis, or to contractors who handle billings for DOL. ( Tr. 39) Decisions relating to allowable and non allowable medical expenses are specified in detail, and are made by DOL.[14] The Department, from time to time, amends its Provider Manual to include coverage of new prescription drugs and other medical services generally accepted in the medical field to be appropriate for the treatment of chronic lung disease. DOL's medical policy is an ongoing process which is periodically updated based on current

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[13] "The purpose of this Provider Manual is to assist [health care professionals, i.e. physicians, hospitals, pharmacies, DME providers, consultants, and other providers of health care services] with basic information about processing bills in the Federal Black Lung Program" The Manual is intended to provide a concise explanation of Black Lung billing instructions and procedures. It sets forth covered medical treatment services, where no certificate of medical necessity is required; covered medical treatment services which require a certificate of medical necessity, and medical treatment services which are not covered. *"Preface", Black Lung Provider Manual* (1985)

Section 2.5 states: "For informational purposes, the following is a partial list of services and conditions that are not Black Lung related and therefore, are not reimbursable .... organ transplants...." *Id*., p. 2-15. *See also 1990 Black Lung Provider Manual: Pharmacy, Appendix 1-1, Non-Covered Services (Partial Listing),*

[14] Consistent with the regulations, the functional responsibilities of DOL are stated in the Manual to include the enrollment of providers in the Black Lung Program, approval or disapproval of certificates of medical necessity, reimbursement to eligible miners and providers for treatment of black lung disease, establish program medical policy, payment disbursements, and review of unusual circumstances and case. CSC's responsibilities are strictly ministerial. See the Manual, at p. 1-2

medical knowledge and procedures. The Agency responsible for conducting reviews and authorizing changes is OWCP, Employment Standards Administration ("ESA") (Tr. 32)

Ms. Rhonda Alderman, Branch Chief, Standards, Regulations and Procedures, Division of Coal Mine Workers' Compensation, testified on behalf of the Director, OWCP. According to her testimony, as of the date of the hearing, lung transplants were still listed as a non-covered medical expense in the 1985 Black Lung Provider Manual and 1990 Black Lung Pharmacy Manual. (Tr. 45). The instant case is the first and only case, in which a lung transplant had been approved by the Director for the treatment of pneumoconiosis. (Tr. 64). During the experimental stages in the development of lung transplant procedures in the medical community, OWCP declined to recognize the procedure as a covered expense under the Act. OWCP now recognizes that the lung transplant procedure has progressed from an experimental stage to an "interim" stage, in which the survivor rate has increased and the medical centers approved by HCFA (Heath Care Financing Administration) [15] to conduct the procedures have become more skilled. (Tr. 46-47). OWCP's current procedure is to make individual determinations on a case by case basis, where a lung transplant may be sought, and to use HCFA's guidelines when determining whether a candidate is appropriate for a lung transplant. [16] In determining the allowable and appropriate costs for a lung transplant procedure and attendant medical care, DOL uses Medicare Guidelines as a starting point and considers the guidelines of other groups that pay medical benefits for like services, i.e. the United Mine Workers (Tr. 55). In this case, OWCP relied on the evaluation submitted by Dr. James Lloyd, Medical Director, Lung Transplant Program, Vanderbilt University Medical Center, and the medical opinions of Drs. Leon Cander and Dr. Michael Sherman. The standard applied in approving the procedure for the deceased miner was whether the procedure was necessary and related to the treatment of the miner's coal workers' pneumoconiosis. (Tr. 49-50)

Section 2.5 of the provider manual was in effect on the date of the miner's last employment in the mines, and at all times relevant to this proceeding. The section unequivocally excludes organ transplantations from covered medical benefits under the Black Lung Act.

The Employer claims that DOL's request for reimbursement of medical expenses attendant to the lung transplant procedure violates the APA, because it seeks to retroactively impose coverage for a procedure that it has consistently been non-covered under the Act, without publishing notice or seeking comments from affected parties. Employer argues that the manual provision is a "substantive" rule, rather than an "interpretative" rule which would be exempt from APA notice and comment requirements.

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[15] HCFA is the agency charged with responsibility of administering the Medicare Program, under Title XVIII of the Social Security Act, the nation's government sponsored health insurance program that pays for covered medical services provided to eligible aged and disabled persons. HCFA contracts with fiscal intermediaries as the Secretary's (Health and Human Services) agents in administering the program. *See 42 U.S. §1395h* The fiscal intermediaries are insurance companies which, pursuant to the instructions of the Secretary and HCFA, process and review claims to determine (1) whether they are for covered services; and (2) the appropriate amount of the reimbursement. *See generally Schwartz v. Medicare*, 832 F. Supp. 782, 784 (N.D. N.J. 1993).

[16] See Vanderbilt Medical Center Lung Transplant Protocol which was approved by HCFA in 1995. (DX 38)

Employer asserts that DOL's determination not to adhere to Section 2.5 of the manual was not a matter committed to agency discretion. Instead, Employer asserts that the agency's action created a "substantive rule"governing the conduct of the parties, and that the public affected by that "rule" should have been given notice and the opportunity to comment.

As stated previously, the Director's position is that this case is limited to one issue, i.e. whether the lung transplant and post operative tests and ancillary expenses and treatment constituted medical care required for the treatment of the miner's coal workers' pneumoconiosis under Section 20 C.F.R. 725.701(b). [17] In response to Employer's arguments, the Director cites *Brock v. Cathedral Buffs Shale Oil*, 796 F. 2d 533 (D.C. Cir. 1986) for the authority that the Provider Manual provision is an interpretative rule. Relying on *American Hospital Association v. Bowen*, 834 F. 2d 1037, 1045 (D.C. Cir. 1987), the Director argues that the Manual provision in issue is not a legislative rule within the meaning of the APA. Thus, the equitable principle of estoppel has no application, (*See Response to Motion for Summary Decision*, p. 8) Finally, the Director states that, assuming the decision to approve the transplant can be considered a retroactive application of a "rule," or an attempt to rescind a legislative rule without notice and comment, estoppel would not apply since the Employer has failed to show reliance on the rule to its detriment. As authority for this position it cites *Heckler v. Community Health Services*, 467 U.S. 51 (1984).

(1) Applicability of the Administrative Procedure Act

Section 533(c) of the APA provides that an agency shall give interested persons an opportunity to participate in rulemaking through the submission of written data, views or arguments. The purposes of the notice and comment requirements of the APA are twofold: "to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies," *Batterton v. Marshall*, 648 F. 2d 694, 703 (D.C. Cir. 1980) and "to [ ] assure that the agency will have before it the facts and information relevant to a particular administrative problem, as well as suggestions for alternative solutions." *Guardian Federal Savings & Loan Insurance Corp.*, 589 F. 2d 658, 662 (D.C. 1978). Notice and comment requirements do not apply to: (1) interpretive rules, general statements of policy, or rules of agency organization, practice, or procedure; or (2) an agency's good cause finding that notice and public procedure are impracticable, unnecessary, or contrary to public interest. 5 U.S. C. §553(b). The Section 553(b) exemption allows agencies to explain ambiguous terms in legislative enactments without having to undertake cumbersome rule making proceedings. However, these exceptions to the notice and comment requirements of the APA have been narrowly construed by the Courts so as not to defeat the purposes of the APA. *National Association of Home Health Agencies v. Schweiker,* 690 F. F. 2d 932, 949 (D.C. Cir. 1982), *cert denied*, 459 U.S. 1205, 103 S. Ct. 1193 (1983), and to preserve agency flexibility in dealing with limited situations where substantive rights are not at stake. I now turn to whether the provisions of DOL's provider manuals or DOL's

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[17] Stated slightly differently, the issue is whether employer is required to pay for a lung transplant for the deceased miner as "medical, surgical, and other attendance and treatment" required by the miner's pneumoconiosis and ancillary pulmonary conditions and disability. (33 U.S.C. 907). *See Glen Coal Co. v. Seals* 147 F. 3d 502, 514 (6th Cir. 1998).

determination to approve the lung transplant for the miner contrary to the provisions of the provider manual fall within either the interpretive rule or policy statement exceptions to Section 533(b).

Section 551(4) defines "rule" as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy... and includes the approval or prescription for the future of rates, ... services or allowances ... or costs ..." There are two types of rules: legislative[18] and interpretive. "Regulations, substantive rules or legislative rules" create law, whereas interpretative rules are statements of what an administrative officer thinks the statute or regulation means ... Substantive rules are ones which "grant rights, impose obligations, or produce significant effects on private interests ..." or which "effect a change in existing law or policy." *American Hospital Association v. Bowen*, 834 F. 2d 1037 9D.C. Cir. 1987). Legislative rules create new law, rights, duties in what amounts to legislative acts. The rule itself is the primary source of the legal obligation. Interpretative rules interpret or clarify existing statutes or legislative regulations, and are issued by an agency to advise the public of the agency's construction of the statutes and rules it administers". *State of Ohio Dept. of Human Services v. U.S. Dept Health & Human Services, HCFA*, 862 F.2d 1228 (6th Cir. 1988). They do not have the full force and effect of a substantive rule but are in the form of an explanation of particular terms. *Guardian Fed. Sav. & Loan v. Fed. Sav. & Loan Ins. Corp.*, 589 F. 2d 658, 664-65 (D.C. Dir. 1978). Interpretive rules do not create rights, foreclose alternative courses of action, or conclusively affect rights of private parties. *Batterton v. Marshall*, 648 F. 2d 694, 701-709 (D. C. Cir. 1980). The statute is the basis for any legal obligation of imposition of liability. The Courts and the commentators generally agree that the distinction between substantive and interpretative rules is "fuzzy". *See American Hospital Association v. Bowen, supra, K. Davis, Administrative Law Treatise Sec. 7* (2 Ed. 1983), and that the determination of whether an agency's action is interpretive or legislative must be made on a case by case basis.

The manual provision at issue is an interpretive rule which is exempt from the notice and comment requirements of the APA. OWCP's approval of the lung transplant, while inconsistent with the Manual guidelines, is consistent with the statute and the implementing regulation. As such, I believe the agency's action constitutes a lawful exercise of agency discretion which it explicitly retained under the Manual's guidelines. In the case at bar, OWCP follows much the same procedure used by HCFA, prior to the adoption of a national policy of medicare coverage for lung transplants, with one significant difference.[19] OWCP has not relinquished its discretion to determine when a lung transplant is reasonable

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[18] Legislative rules are also referred to as "substantive" rules. *See Deference Running Riot: Separating Interpretation and Lawmaking under Chevron,* Michael Herz, 6 ADMLJAMU 187, Summer 1992, n. 19, citing *Chrysler Corp v. Brown*, 441 U.S. 281, 302(1979) (referring to a "substantive rule – or a legislative-type rule"); *Batterton v. Francis*, 432 U.S. 416, 425 n. 9 (1977) (referring to "[l]egislative, or substantive regulations"; Schwartz, *Administrative Law* 180-81 (3d ed 1991); United States Dept. of Justice, *Attorney General's Manual on Administrative Procedure* Act 30, n. 3 (1947) (using term "substantive rules"; *See also* 2 Kenneth Culp Davis, *Administrative Law Treatise* §7:9. At 45-48 (2d ed. 1979)(stating that "legislative rules" is the preferable term, because "substantive" means "nonprocedural".)

[19] Employer points to the procedures used by HCFA to implement the Medicare criteria for lung transplants, suggesting that HCFA considered its announcement of a national coverage policy for heart-

and necessary for the treatment of pneumoconiosis to the physicians who provide the medical services. In fact, under the provisions of the Provider Manual, it has specifically retained the discretion to review unusual circumstances and cases and to establish program medical policy. (Manual, Sec. 1.2) Thus, on a case by case basis, OWCP approves lung transplants as necessary and related to the treatment of a miner's pneumoconiosis, prior to the surgery being performed. This does not appear to be an unreasonable exercise of discretion, given (1) the extremely limited number of lung transplants (no more than two) recommended for the treatment of beneficiaries' coal workers pneumoconiosis; and (2) the current case by case approach ensures against inconsistencies in the criteria applied in making decisions that the procedure is necessary for the treatment of coal workers' pneumoconiosis.

Employer argues that when the agency's acts as it has in this matter, it engages in substantive rule making, and that such action adversely impacts on its responsibilities to provide insurance coverage for the lung transplant. Specifically, Employer argues that, because lung transplants were excluded from coverage, it did not pre-fund this claim for that cost and cannot now do so under state regulatory requirements. Employer has not introduced evidence to substantiate its claim that it relied on the guidelines to its detriment. I find no factual basis in this record to make findings relating to the impact of the agency's action on Employer's statutory duty as the self-insured coal mine operator responsible for the payment of benefits. The agency's action in this case did not result in a new legal standard. The Employer is required to do no more than it was required to do under the statute and regulations prior to the

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lung transplants to be "substantive" rule making under the APA. However, the two federal programs are too dissimilar to be analogous. Medicare is a national health insurance program, which is administered under a statutorily created structure substantially different from and more complex than the Black Lung program. Title XVIII of the Social Security Act governs the Medicare program, which provides for broad categories of medical benefits and direction as to the manner in which payment is made for medical services. Congress left to the Secretary the discretion to determine the question of coverage of specific services which would invariably arise. 60 F. Reg. 6537 (2/2/95)

Until 1995, the Medicare program did not have a national coverage policy on lung and heart-lung transplants. In the absence of a national policy, the contractors that process Medicare claims were authorized to develop Medicare coverage policy for their services using medical literature, the advice of medical consultants and local medical societies. In 1995, HCFA published criteria for Medicare coverage of lung transplants, as reasonable and necessary services when furnished to patients with progressive end stage pulmonary or cardiopulmonary disease, which met specified criteria.

In 1995, HCFA implemented its national coverage policy as an interpretative rule. Section 1869(b)(3)(B) and 1871(a)(2) of the Act specifically exempts national coverage decisions from notice and comment rule making process required by Section 553 of t he APA. The Notice published in the Federal Register stated that, while HCFA was seeking public comments on the criteria for Medicare coverage, it was also proceeding to final notice. HCFA explained that it had previously used the comment process in discontinuing coverage procedures. However, it believed the lung transplant coverage issue to be one of the establishment of a national policy where no policy previously existed. As such, although it published notice of the criteria for Medicare coverage of lung transplants, it finalized that policy under the exemption clause of the APA rule making procedures. *60 F. Reg. 6537-41*. In short, while it was not required to publish notice, it did so to obtain public comment.

agency's coverage determination. Any impact DOL's deviation from the guidelines in the Manual may have had on Employer's interest is incidental to its existing duty to pay medical benefits related to the treatment of coal workers' pneumoconiosis.

The underlying purpose of the statutory provision is to ensure that coal miners are provided medical benefits in the treatment of disabling coal dust related lung disease. The Manual provision at issue herein does not change any existing law Thus, whether an item or service under the Manuals is covered or excluded, or whether OWCP makes a case by case determination to create a modification to the general provisions in the Manual, the end result is that the parties are bound by the same regulatory standard. Neither the manual provisions nor OWCP's action in this case changes the meaning of a validly adopted regulation, which requires the Employer to pay medical benefits related to the miner's coal workers' pneumoconiosis. In conclusion, I find that the Manual provision is an interpretive rule exempt from the notice and comment requirements of the APA. The rule neither creates a binding new law nor conflicts with the lawfully promulgated regulations. OWCP's decision to carve out an exception to the Manual's exclusion from coverage clause in the case of Mr. Davis is supported by sufficient factual foundation and is documented by reasoned medical opinions. I reach this conclusion recognizing OWCP's need to be given latitude to modify and revise its Manual guidelines consistent with the underlying legislative intent, in response to changing circumstances – particularly where scientific advances and generally accepted medical practices dictate changes in medical care for cardiopulmonary related conditions.

3. Whether the Director's Authorization of the Miner's Lung Transplant as a Covered Reimbursable Medical Expense under the Black Lung Act was Arbitrary and Capricious Agency Action.

Under Section 706(2)(A), an agency's action may be set aside if found to be arbitary, capricious, an abuse of discretion, or otherwise not in accordance with law. *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 103 S. Ct. 2856 (1983). The inquiry is whether the agency acted reasonably – i.e., whether its articulated explanation provides a rational connection between the facts found and the choice maid. An agency rule would be arbitrary and capricious if the agency relied on factors Congress had not intended it consider, failed to consider an important aspect of the problem, or offered an explanation that is contrary to the evidence. *Bowman Transportation Inc., v. Arkansas-Best Freight System*, Inc. 419 U.S. 281, 285 (1974). *See also Agent v. Halala*,, 70 F. 3d 610 (CA.D.C. 1995). In the case at bar, the record contains sufficient support for the factual bases of the agency's conclusions. The weight of the reasoned medical opinions support the determination that the lung transplant procedure was related to and necessary for the treatment of the miner's black lung disease The witness for OWCP at the hearing adequately explained the basis for the agency's decision, and the policy considerations underlying the decision are reasonable. My reasons for finding that the agency's exercise of discretion in this matter was permissible are discussed above at pp. 13-14, supra., and will not be reiterated.

For the foregoing reasons, Employer's Motion for Summary Decision is Denied. The Director is entitled to reimbursement of the reasonable medical expenses incurred in the treatment of the miner's coal workers' pneumoconiosis, including but not limited to the expenses associated with his lung transplant.

ORDER

The Employer shall reimburse the Black Lung Disability Trust Fund for the reasonable medical expenses attendant to the miner's lung transplant.

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MOLLIE W. NEAL
Administrative Law Judge

**NOTICE OF APPEAL RIGHTS:** Pursuant to 20 C.F.R. 725.481, any party dissatisfied with this Decision and Order may appeal it to the Benefits Review Board within thirty (30) days from the date of this Decision and Order by filing a notice of appeal with the Benefits Review Board, Post Office Box 3601, Washington, D.C. 20013-7601. A copy of the notice of appeal must also be served on Donald S. Shire, Esquire, Associate Solicitor for Black Lung Benefits, Francis Perkins Building, Room N-2605, 200 Constitution Avenue, N.W., Washington, D.C. 20210.